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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,701	11/06/2001	Richard C. Willson	96605/13UTL	7906

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EXAMINER

BURKHART, MICHAEL D

ART UNIT PAPER NUMBER

1633

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,701

Applicant(s)

WILLSON ET AL.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/8/2005, 11/5/2005, and 2/7/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22-26, 29-32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 18-20, and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17, 22-25, 29-32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt and entry of the amendment dated 2/7/2006 is acknowledged. After entry of the amendment, claims 1-20, 22-26, 29-32 and 34-37 are pending. Claims 1-9, 18-20, and 26 remain withdrawn as drawn to non-elected inventions. Claims 10-17, 22-25, 29-32, and 34-37 are under examination.

Claim Objections

Claim 36 is objected to because of the following informalities: "comprising comprising" should be "comprising". Appropriate correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 16 recites the term "DNA and/or RNA compound" not found in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 17, 29, 30, 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 16 is rejected as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention, the claim must recite a method step that provides for the results of the method as claimed. The preamble recites a method for purifying a "DNA and/or RNA compound", yet the method steps do not even recite such a compound being contacted with the IMAC ligand. Rather, a crude mixture comprising a "target compound" and contaminants is contacted with the IMAC ligand. Furthermore, the term "the compound", to be recovered in the last line of the claim, is ambiguous because the claim previously recites two "compounds": the DNA and/or RNA compound in the preamble, and the target compound in the first recited method step. This rejection affects all dependant claims. **This is a new rejection.**

Claim 36 recites a method for separating compounds, but the first method step recites passing RNA and/or DNA through an IMAC column. Therefore, it appears no compounds were ever passed through the IMAC column, thus it is unclear how they could be collected in the final method step. There is no nexus between the first method step and the preamble or final step. This rejection affects all dependant claims. **This is a new rejection necessitated by amendment of the claims.**

Claim 17 contains improper alternative language, as the claim states: "selected from the group consisting of" but proceeds to identify a Markush group with or terminology. This constitutes improper Markush format. See MPEP 2173.05(h). **This rejection is maintained for reasons made of record in the Office Action dated 2/8/2005.** Applicants assert "or" has been amended to "and", but no such amendment can be found in the claim.

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Claims 29 and 30 depend from canceled claim 27. No other pending claim reasonably recites the subject matter found in these claims (e.g. "poly(A) mRNA", "T-rich regions", "G-rich regions"). Hence it is unclear what the subject matter of these claims might be. **This is a new rejection necessitated by amendment of the claims.**

Claim 32 recites a method to purify a crude compound "containing a non-shielded purine..or pyrimidine moiety from a mixture containing DNA and/or RNA, which comprise compounds with and without a non-shielded purine..or pyrimidine." It is unclear what comprises the "compounds with and without a non-shielded purine..or pyrimidine" in the context of the claim, as either the crude compound of the preamble or mixture containing DNA and/or RNA can be read to comprise this limitation. Furthermore, it is unclear which "compound" is to be recovered in the last line of the claim, as the term "compound" is used in the claim to recite two distinct entities: the "crude compound" of the preamble, and the "compounds with and without a non-shielded purine..or pyrimidine." Therefore, the metes and bounds of the claim subject matter are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immobilized metal "ions", does not reasonably provide enablement for immobilized metal "atoms". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention

commensurate in scope with these claims. **This rejection is applied to a new claim for reasons made of record in the Office Action dated 2/8/2005.**

Claim 23 recites a method for separating compounds using “immobilized metal atoms and/or ions.” Claims 10, 11, 21, 22, 24, and 25 were rejected in the previous Office Action under this statute for the same reasons which are applied her as before, i.e. the instant disclosure is not enabling for using metal atoms in the claimed methods. Claim 23 was inadvertently left out of the rejection, and hence stands rejected.

Claims 14, 15, and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for contacting a liquid food stuff, such as a broth, with an IMAC ligand containing substrate, does not reasonably provide enablement for contacting of solid food with an IMAC ligand substrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This rejection is maintained for reasons made of record in the Office Action dated 2/8/2005, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 2/7/06 have been fully considered but they are not persuasive. Applicants assert that the foodstuff can be pretreated with a digestion enzyme, which will facilitate contact with solid food stuff. Such assertion is not convincing. Such a step is not recited in claim 14, and claim 15 and 31 only recite DNA digestion enzymes. It is unclear how DNA digestion enzymes could serve to render solid food, such as an apple, into a liquid form in

which the claimed IMAC ligand could come into contact. Hence, it is still considered that the disclosure is enabling only for liquid food stuffs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13, 22-25, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Petty (Curr. Protocols Mol. Biol., 1996). **This rejection is maintained for reasons made of record in the Office Action dated 2/8/2005, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 2/7/06 have been fully considered but they are not persuasive. Applicants assert that: 1) the claims have been amended to recite that DNA and/or RNA is present and collected; 2) Petty is directed to protein purification, not nucleic acid purification; 3) Petty teaches performing the methods in the cold, which is not preferred in the instant methods; 4) Petty teaches addition of protein-destroying enzymes, which destroy the DNA and RNA moieties sought to be purified by the instant invention; 5) Petty teaches addition of DNase, which would be disastrous in the instant invention; 6) Petty teaches purification only from *E. Coli*, whereas the instant invention uses much broader sources.

Regarding 1), 4), and 5), at the very least RNA is present in the bacterial cell lysates of Petty and thus is anticipatory of the claims as amended. There is no amendment stating that

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DNA/RNA is collected, furthermore the limitation was found in original claim 12, and considered anticipated by the elution conditions taught by Petty (sentence bridging pages 11-12 of the previous Office Action). It is unclear how a protein-destroying enzyme could degrade DNA and/or RNA as asserted by applicants, and furthermore the step referenced by applicants is an addition of protease inhibitors, not proteases. The step of adding a DNase I, even if it were to degrade all DNA in the lysate, would still leave individual nucleosides and RNA available to bind to the Ni-NTA resin. Regarding 2), this point is not in dispute, however, the argument made in the previous Office Action is that Petty inherently teaches the claimed invention. Such a finding of inherency does not require that the claimed feature be recognized at the time of invention/disclosure (see MPEP 2112). Regarding 3) and 6), there are no temperature or source limitations in the instant claims, hence the methods of Petty are still anticipatory.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Hubert (1981). **This rejection is maintained for reasons made of record in the Office Action dated 2/8/2005, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 2/7/2006 have been fully considered but they are not persuasive. Applicants assert that: 1) Hubert does not separate or collect DNA or RNA, but rather small mono- or dinucleotides; 2) Hubert does not recover products from the adsorbent; 3) Hubert doesn't test his procedure with shielded purines or pyrimidines; 4) Hubert does not teach how to purify nucleotides from cells or tissues.

Regarding 1), the claim recites a DNA and/or RNA compound, not DNA or RNA. Lacking any guidance in the specification, a nucleotide is considered to be a "DNA and/or RNA compound" because DNA and RNA are made up of nucleotides. Furthermore, the preamble of the claim is treated only a statement of intended use because the method steps of the claim do not recite DNA and/or RNA. Thus, the preamble is given no patentable weight. Regarding 2), it is clearly taught that CMP and GMP are recovered from the copper affinity column (Figure 1 and the previous Office Action. Regarding 3) and 4), these are not limitations found in the instant claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huber (1981) in view of Yarchoan (1986)(hereinafter Yarchoan-1), Yarchoan (1989)(hereinafter Yarchoan-2). **This rejection is maintained for reasons made of record in the Office Action dated 2/8/2005, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 2/7/2006 have been fully considered but they are not persuasive. Applicants assert that: 1) Hubert is deficient (presumably for reasons asserted above) and that the Yarchoan references do not make up this deficiency; 2) the Yarchoan references do not teach metal affinity chromatography.

Regarding 1), Hubert still applies for reasons recited above. Regarding 2), in response to applicant's arguments against the references individually, one cannot show nonobviousness by

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attacking references individually where the rejections are based on combinations of references.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER